

## REMARKS

1. Rejection of Claims 1-6, 10-12, 14-20 and 25 under 35 U.S.C. 102(b)

Claims 1-6, 10-12, 14-20 and 25 were rejected under 35 U.S.C. 102(b) as anticipated by Cohen et al., for the reasons of record.

Initially, Applicants note that the apparatus disclosed by Cohen et al. and that described in the present application are directed to entirely different arts within the general field of stimulation of skeletal muscles and associated nerves. Cohen et al. describes a device in which a user inputs a command which results in electrical stimulation of a nerve to move the muscle in the manner desired by the users. In other words, the "Six Million Dollar Man"-like "bionic" system (Cohen, Summary of the Invention, throughout document) of Cohen theorizes that minute stimulators implanted near or on skeletal nerves may be used to replace or enhance motor nerve control in individuals with damage to their brains, spinal cords or other nerves. In contrast, the present invention is directed to the much more practical, cost effective, and realizable goal of providing biofeedback to patients who are attempting to regain control over their muscles by attempting to move a given muscle, which the apparatus senses and responds to by providing stimulation to the muscle when a given threshold is reached.

Applicants response to the particular aspects of the Cohen et al. invention are as follows:

a. Cohen et al. does not prompt an individual to contract an impaired muscle, as suggested by the Examiner, (citing col. 1 para 005). In fact, Cohen et al. does just the opposite because it provides complete movement control in response to a movement

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command by the individual, rather than the individual himself attempting to move the muscle. Contrast this with the present invention in which the individual himself, using his own physical exertion, attempts to make movements, thus retraining himself to control muscle movement after an injury event.

Further, the referenced paragraph of Cohen (col. 1 para 005) discusses the inadequacies of the prior art and is not a disclosure describing the Cohen et al. invention itself. Even so, the paragraph in question discusses systems in which a muscle is stimulated by an external command, rather than by an attempt by the patient to move the muscle himself.

b. Cohen et al. does not detect an electrical signal with the impaired muscle using electrodes placed on the individual's skin. However, in order to add greater specificity to the claims, Claims 1, 12, 22, 23, and 25 have been amended to specify that the present invention detects an electrical signal from within an impaired muscle generated by a patient's attempt to contract the muscle. Cohen et al. does not teach or suggest detection of such as signal.

c. Regarding the Examiner's point that both Cohen et al. and present invention transmit the electrical signal to a microprocessor, Applicants respectfully note that the paragraph cited by the Examiner (col. 4, para 0031) refers to a microprocessor outputting signals to the electrode array, rather than receiving signals from it. Recall that Cohen et al. is directed to a system that replaces motor control of the individual, rather than attempting to improve it, and therefore Cohen et al. has no need to monitor electrical output from the

muscle or nerve, just the location of the limb to ensure that the system is moving the limb to the desired position.

d. Cohen et al. does not check the pattern of the electrical signal against a mathematical algorithm because "the electrical signal" referred to in the present invention and rejected claims is not the same "electrical signal" contemplated by Cohen et al. That is, subpart "d" of present claim 1 is not read in a vacuum, in the context of the entire claim subpart "d" refers back to subparts "a" and "b" which recite an electrical signal generated by the individual's attempt to contract the muscle.

The cited paragraph refers to the ability of the Cohen et al. system to analyze information generated by the "disposition sensors", that is, sensors which tell the Cohen et al. system the position of the muscle/limb in which movement was sought rather than an electrical signal generated by the patient's muscle. Therefore, while both systems do employ mathematical algorithms, the algorithms are for the analysis of completely different things and Cohen et al. does not anticipate the present claim limitation.

e. Cohen et al. does not determine whether or not an attempt to move the impaired muscle has been made. As noted earlier, the cited paragraph of the background section does not refer to the Cohen et al. apparatus. Again, the Cohen et al. device does not utilize any control or attempt at control of the muscle initiated by the individual but instead seeks to replace muscular control with "bionic neurons" that stimulate muscles in response to a computer command. Thus, the individual never makes an "attempt" for the Cohen et al. apparatus to sense or analyze. In order to add specificity to the claim, part "e" of Claims 1,

22, and 25 have been amended to recite an attempt to move the muscle made by the patient.

f. Cohen et al. does not measure "the strength of the electrical signals" as recited by the present claims. As set out in section d above, "the electrical signal" being referred to in each case is different. Further, the Cohen et al. invention, being a motor control unit, does not utilize a threshold as a criterion for movement. If the individual commands a movement, the Cohen et al. invention tries to fulfill that command and execute the movement. The Cohen et al. device then receives signals regarding the location of the limb and compares the signal to a position value to insure the proper movement has occurred. Contrast this with the therapeutic and rehabilitation device of the present invention which establishes a threshold as a criterion for electrical stimulation. If that threshold is not met, the individual does not receive any "reward", i.e., electrical stimulation.

Therefore, while each device does receive signals and each does measure the strength of signals against threshold values, because of the different signal sources Cohen et al. does not anticipate the present claims any more than an electric dish washer anticipates the claims (when it receives an electrical feedback telling it that the dishes are clean by comparing the clarity of the outflow water against a threshold clarity). Again, each subpart of the present claim must not be read in a vacuum.

g. Cohen et al. does not send an electric current if the strength of "the electric signal" is larger than a first threshold value, for the reasons cited above with respect to the meaning of "the electrical signal".

h. Regarding the arguments directed specifically to claims 2, 16, 17, 3-6, 10, 14, 15, 18, 19, 11 and 20 set out on pages 4-5 of the Office Action, Applicants note that these arguments are directed to various technical features of the present invention as recited in the dependent claims, such as visual displays, data recording devices, and methods and devices for reducing electrical noise. Such technical features are recited by Cohen et al. as well as many other electronic devices. However, all of the above-referenced claims depend from and thus contain all the limitations of the independent claims describing the novel and patentable features of the present invention, as set forth above. Accordingly, the arguments regarding dependent claims 2, 16, 17, 3-6, 10, 14, 15, 18, 19, 11 and 20 are addressed by Applicants' arguments as set forth above directed to claim 1.

i. Regarding the Examiner's arguments with respect to independent Claim 12, Applicants note that the arguments largely parallel the Examiner's arguments presented with respect to claim 1. Accordingly, Applicants' responses above apply equally to the rejection of claim 12. To reiterate, Cohen et al. describes a system in which a command input into a computer results in electrical stimulation of nerves to achieve a desired movement of a muscle whereas the present invention is a rehabilitative device in which an individual attempts to move an impaired muscle and receives electrical stimulation of the muscle once an "attempt" is registered, thus allowing the individual to retrain muscle movement. Accordingly, Cohen et al. does not detect signals generated during an attempt to move a muscle, does not decipher electrical signals made during an attempt to move a muscle or determine whether such an attempt meets a threshold level, and does not provide

the individual with electrical stimulation of the muscle when a sufficient attempt to move the muscle has been made.

In view of the foregoing, Applicants respectfully assert that Cohen et al. does not teach each and every element of the claimed invention, as required to make a proper rejection under 35 U.S.C. 102(b) and request that the rejection of Claims 1-6, 10-12, 14-20 and 25 under 35 U.S.C. 102(b) be withdrawn.

2. Rejection of Claims 7-9 and 13 under 35 U.S.C. 103(a)

Claims 7-9 and 13 were rejected under 35 U.S.C. 103(a) as obvious over Cohen et al. in view of Gesotti, for the reasons of record. Briefly, Cohen et al. was presented as disclosing the claimed invention as set forth in the Examiner's arguments under 35 U.S.C. 102(b), except that Cohen et al. does not disclose the use of visual, sensory or auditory cues. Gesotti was presented as disclosing a stimulator device that teaches visual, sensory and auditory cues.

Applicants respectfully traverse the Examiner's rejection. Initially, applicants concede that Gesotti, and many other electronic devices utilize visual, sensory or auditory cues as a means of signaling that a desired result has been achieved. Applicants assert that the arguments presented regarding Cohen et al. in response to the rejection under 35 U.S.C. 102(b) may be equally applied to this rejection.

Similar to the argument set forth in section h of the response to the rejection under 102(b) above, dependent claims 7-9 and 13 set forth technical features that are ancillary to the novel and patentable invention set forth in the independent claims from which they

depend. Accordingly, since Cohen et al. fails to teach or suggest the invention as set forth in the independent claims for the reasons presented above, the addition of Gesotti in making a rejection under 35 U.S.C. 103 must also fail because the combined references still fail to teach or suggest all the features of the claimed invention.

In view of the foregoing, Applicants respectfully request withdrawal of the Examiner's rejection of Claims 7-9 and 13 under 35 U.S.C. 103(a).

3. Rejection of Claims 21-24 under 35 U.S.C. 103(a)

Claims 21-24 were rejected under 35 U.S.C. 103(a) as obvious over Cohen et al. in view of the general conditions available in the art, which would make the discovery of optimum or workable ranges a matter of only routine skill (citing *In re Aller*).

Initially, Applicants assert that the arguments presented regarding Cohen et al. in response to the rejection under 35 U.S.C. 102(b) may be equally applied to this rejection. That is, Cohen et al. fail to teach a method or device that prompts an individual to attempt to move a muscle, instead Cohen et al. does the opposite by replacing the attempt with an apparatus that moves the muscles by electrical stimulation of the nerve. Accordingly, Applicants again assert that Cohen et al. fails to teach each and every element of the claimed invention, regardless of the "optimum and workable ranges" set forth in claims 21-24.

Further, the "common knowledge" regarding optimal ranges cannot be imputed from one device to the other due to the fact that they are not are the same sort of device. Since the two inventions are so vastly different from concept to execution, there is no

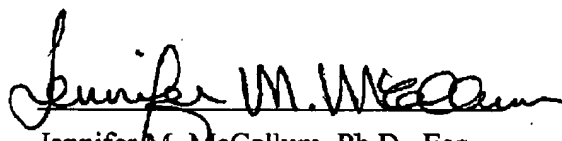
reasonable expectation that the levels (0.2 – 2000  $\mu$ V) and sampling rate indicated (3000 samples/sec.) in the present claims would be proper for the apparatus of Cohen et al., particularly in view of the fact that its objective is to transmit signals to muscles, rather than sense signals coming from them.

In view of the foregoing, Applicants respectfully request that the rejection of Claims 21-24 under 35 U.S.C. 103(a) be withdrawn.

In view of the foregoing, Applicants respectfully assert that all pending claims are in a condition for allowance.

Respectfully Submitted,

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